

Subpart B—Eligibility To Purchase 340B Drugs

§ 10.10 Entities eligible to participate in the 340B Drug Pricing Program.

Only organizations meeting the definition of a covered entity and listed on the 340B database are eligible to purchase covered outpatient drugs under the 340B Program. A covered entity remains responsible for complying with all other 340B requirements and applicable Federal, state, and local laws.

Subpart C—Drugs Eligible for Purchase Under 340B

§ 10.20 Drugs eligible for purchase under 340B.

The definition of a covered outpatient drug has the meaning given to such term in section 1927(k)(2) of the SSA except as provided in § 10.21 of this part.

§ 10.21 Exclusion of orphan drugs for certain covered entities.

(a) *General.* For the covered entities described in paragraph (b) of this section, a covered outpatient drug does not include orphan drugs that are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated under section 526 of the FFDCA. A covered outpatient drug includes drugs that are designated under section 526 of the FFDCA when they are transferred, prescribed, sold, or otherwise used for any medically-accepted indication other than treating the rare disease or condition for which the drug was designated under section 526 of the FFDCA.

(b) *Covered entities to which the orphan drug exclusion applies.* (1) The exclusion of orphan drugs when used to treat the rare disease or condition for which the drug was designated under section 526 of the FFDCA from the definition of covered outpatient drugs described in paragraph (a) of this section shall only apply to the following covered entities: free-standing cancer hospitals qualifying under section 340B(a)(4)(M) of the PHSA, critical access hospitals qualifying under section 340B(a)(4)(N) of the PHSA, and rural referral centers and sole community hospitals qualifying

under section 340B(a)(4)(O) of the PHSA. The exclusion does not apply to the remaining covered entities that meet the 340B Program eligibility requirements.

(2) When an entity described in this paragraph (b) meets more than one eligibility criterion as a covered entity, the entity shall select its eligibility type and notify the Secretary. These eligible entities are limited to participating in the 340B Program under only one covered entity hospital type and shall abide by all applicable restrictions and requirements for that entity type. A covered entity subject to this provision may only change its participation type to another hospital entity type on a quarterly basis upon express written confirmation from the Secretary.

(c) *Covered entity responsibility to maintain records of compliance.* (1) A covered entity listed in paragraph (b) of this section is responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the FFDCA. A covered entity listed in paragraph (b) of this section that purchases orphan drugs under the 340B Program is required to maintain and provide auditable records on request which document the covered entity's compliance with this requirement available for audit by the Federal Government or, with Federal Government approval, by the manufacturer.

(2) A covered entity may develop an alternative system by which it can prove compliance. Any alternate system must be approved by the Secretary prior to implementation. Each alternate system of compliance will be reviewed on a case-by-case basis.

(3) A covered entity listed in paragraph (b) of this section that cannot or does not wish to maintain auditable records sufficient to demonstrate compliance with this rule, must notify HRSA and purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used. Once a hospital is enrolled in 340B, it may change its decision to purchase all orphan drugs outside of the